UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,525	09/14/2004	Werner Oberegger	100338.54030US	6721

39290 7590 12/07/2005

DUANE MORRIS LLP
1667 K. STREET, N.W.
SUITE 700
WASHINGTON, DC 20006-1608

EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 12/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/507,525	OBEREGGER ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-154 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-154 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 04/26/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Power of Attorney filed 09/09/05 and 12/10/04, Preliminary Amendment filed 09/14/04, Information Disclosure Statement and Petition to Make Special filed 04/26/05.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 138 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 138 is indefinite in the use of the phrase "salt of bupropion hydrochloride". Hydrochloride (HCl) is a salt of bupropion. It is unclear what a salt of hydrochloride is.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 7, 14-44, 54-65, 67, 68, 72, 75-78, 91-115 and 123-128 are rejected under 35 U.S.C. 102(b) as being anticipated by Seth US 6,143,327.

Seth discloses a delayed release tablet of bupropion HCl comprising a core, a first coating and a second coating (see abstract, and claim 13). Core comprises between 70 and 98% of bupropion HCl, and conventional excipients including lubricant and binder (column 2, lines 18-40). Lubricant includes glyceryl behenate in an amount between 0.5 and 10% (ID). Binder includes polyvinyl alcohol in an amount between 2 and 25% (ID). First coating comprises 20-85% water-insoluble, water permeable film-forming polymer, 5-30% plasticizer, and 10-75% water-soluble polymer (column 3, lines 5-39). Water-insoluble, water permeable polymer includes cellulose ether such as Ethocel® or Ethocel PR100 (ID, and examples). Plasticizer includes polyethylene glycol, such as PEG 1450 (column 3, lines 41-43). Water-soluble polymer includes polyvinylpyrrolidone (ID). Second coating comprises 40-90% methacrylic acid copolymer type C, 10-60% plasticizer, and additive including silicon dioxide (column 3, lines 56 through column 4, lines 1-14; and column 11, lines 35-41). The amount of silicone dioxide is about 18.8% based on the dry weight of the second coating (column 11, lines 35-38 (2.1 mg of silicon dioxide out of 11.2 mg of the total dry weight of the second coating)). Seth also discloses the dissolution profile of after 2 hours from 0 up to 30% of the bupropion HCl is released, after 4 hours from 3 to 22% of bupropion HCl is released, after 6 hours from 15 to 38% of bupropion HCl is released, and after 8 hours more than 40% of bupropion HCl is released (column 4, lines 33-40). It is noted that the release rates between 4 and 6 hours taught by Seth would read over the claimed release profile of after about 4 hours.

It is noted that Seth does not explicitly teach the limitations that the moisture barrier does not function as an enteric coating as defined by a USP test, as well as the dissolution of after about 16 hours. However, it is the position of the examiner that such limitations are clearly inherent, because Seth discloses the claimed dissolution of after about 2 hours, about 4 hours, and about 8 hours, wherein after 8 hours, more than 40% of the bupropion HCl is released, and because Seth discloses the use of the claimed moisture barrier polymer, namely, methacrylic acid copolymer type C or Eudragit L 30 D-55 (see column 3, lies 56-67). When the claimed and prior art products are identical or substantially identical in composition, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Furthermore, products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 6-48, 54-69, 72, 75-115 and 123-140 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seth US 6,143,327.

Seth is relied upon for the reason stated above. Seth does not expressly teach the claimed amounts of enteric polymer and silicon dioxide in claims 66, 85 and 129-154, as well as the weight ratio of water-insoluble polymer to plasticizer to water-soluble polymer in claims 45-48 and 69. However, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to, by routine experimentation determine a suitable weight for the enteric polymer and silicone dioxide, as well as the weight ratio between water-insoluble polymer, plasticizer, and water-soluble polymer, because Seth teaches the claimed percentage weight of water-insoluble polymer, plasticizer, and water-soluble polymer, because Seth teaches about

18.8% of silicon dioxide and about 3.8% of Eudragit L30 D-55 (column 11, lines 35-40), and because Seth achieved the same dissolution profile.

It is further noted that Seth does not explicitly teach the claimed properties at the fasted state in claims 130-140. However, the burden is shifted to applicant to provide data showing that the delayed release tablet taught by Seth does not exhibit the claimed properties since Seth teaches the use of the same ingredients to obtain the same dissolution profile. When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claims 1-140 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seth US 6,143,327, in view of Noack et al. US 2004/0228915.

Seth is relied upon for the reasons stated above. Seth does not expressly teach the weight gain of the coating.

Noack teaches core coated with 15% weight gain shows the greatest extension of release of active over time, while core coated with 7% weight gain shows the least extension of time of active release (paragraph 0085). Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation determine suitable amount of coating depends in the desirability of the release profile to obtain the claimed invention, because Seth teaches the claimed release profile, and because Noack

teaches the amount of coating can be vary and can be modified by routine experimentation depends in the desired release profile.

Claims 141-154 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seth US 6,143,327, in view of Ruff et al. US 5,763,493.

Seth is relied upon for the reasons stated above. Seth does not expressly teach the moisture content, as well as the stability of the tablet. However, the burden is shifted to applicant to provide data showing that the coated tablet taught by Seth does not exhibit the claimed properties since Seth teaches the use of the same ingredients, the same coatings, and the same dosage form for the same active ingredient, namely, bupropion HCl. When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Nonetheless, to be more significant, Ruff teaches a stabilized pharmaceutical solid dosage form suitable for bupropion HCl comprises stabilizer, such as acid to maintain its initial bupropion potency after one year (see abstract). Ruff further teaches the solid dosage form contains at least 90% of undegraded bupropion after one year of storage at temperature ranges between 15-25°C and 35-60%RH (column 1, lines 50-65). Thus, it would have been obvious to one of ordinary skill in the art to modify the bupropion HCl solid dosage of Seth in view of the teaching of Ruff to obtain the claimed invention, because Seth teaches the use of organic acid such as stearic acid (column 2,

line 21; and examples), and because Ruff teaches the use of organic acid as a stabilizer (column 2, lines 8-17).

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ludwig et al., Chungi et al., Chhabra et al., and Zhou et al. are cited as of interest for the teachings of solid compositions comprising bupropion.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Tran
Examiner
Art Unit 1615